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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,634	07/23/2003	Gunther Bellmann	P02819-C1	8078

23702 7590 06/07/2006

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,634	BELLMANN ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request fro RCE, both filed 03/31/2006.

Claims 1-15, 32, 38 and 39 have been canceled.

Claims 16-31 and 33-39 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/31/2006 has been entered.

Specification

2. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 16, 25, 26, 33 and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,599,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to ophthalmic composition comprising the preservative benzyllauryldimethylammonium salt wherein irritation or damage to the eye tissue is avoided even with repeated prolonged use of the composition; and the claims of the issued patent are directed to method of minimizing eye irritation of preserved ophthalmic composition comprising employing benzyllauryldimethylammonium salt in an amount effective to preserve the composition wherein irritation or damage to the eye tissue is avoided even with repeated prolonged use of the composition. Therefore, the present claims and the claims of the issued patent are directed to the same ophthalmic composition and the presently claimed composition has the same property and capable to perform the function claimed by the method of issued patent.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 16, 22, 25, 27, 33, 34, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/15597 ('597).

The present claim 16 and 33 are directed to ophthalmic composition comprising benzyllauryldimethylammonium salt and claim 36 recite the salt as chloride salt. Claim 22 recites single-phase liquid composition. Claim 25 recites the amount of benzyllauryldimethylammonium salt is 0.001 to 0.5 %. Claims 27 and 34 recite the presence of active agent in the composition.

WO '597 disclosed ophthalmic solution, i.e. single phase, comprising benzyllauryldimethylammonium chloride, which reads on claims 16, 22, 33 and 36 (abstract; page 4, lines 23-26). WO '597 disclosed ophthalmic composition comprises preservative consisting of benzyllauryldimethylammonium salt as the only preservative and is present in an amount of 0.005% of the ophthalmic composition, which reads on claims 16, 33, 25 (col.4, lines 9-13; page 6, example B; page 9, claims 1, 4; page 10, claims 6, 9). The composition further comprising active agent and pH adjusting agents, which reads on claims 27 and 34 (page 6, example B). The composition comprises sodium hydroxide to provide pH 6.4-6.6, i.e. physiological pH (page 7, example B).

Benzyllauryldimethylammonium chloride in an amount of 0.005 disclosed by the prior art inherently will not irritate the eye.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 17-21, 23, 34, 26, 28-31, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '597 in view of US 4,271,143 ('143) and US 5,032,392 ('392).

The teachings of WO '597 are discussed above.

However, WO '597 does not each the ophthalmic composition as aqueous based gel as claimed in claim 17, the based gel composition comprising viscosity increasing polymers as claimed in claims 18-20 and 37 and their amounts as claimed in claims 29 and 30, the two phase composition as claimed in claims 23 and 24, the polymers claimed in claim 21, the amount of benzyllauryldimethylammonium salt as claimed in claim 26, vitamin A in the composition as claimed in claim 28, the sorbitan and its amount in the composition as claimed in claims 29 and 30, or the composition in the form of artificial tears as claimed in claim 35.

The amount of the benzyllauryldimethylammonium salt as claimed in claim 26, does not impart patentability to the claims, absent evidence to the contrary.

US '143 teaches ophthalmic composition in the form of gel containing drug in the form of two-phase composition, i.e. drug/polymer dispersion (abstract; col.2, lines 2-25; col.4, lines 10-12). The gel ophthalmic composition has special viscosity and rheology making it free flowing (col.2, lines 35-50). The gel is formed by carboxpolyymethylene polymer and comprises sodium hydroxide to provide physiological pH (col.2, lines 52-60; col.3, lines 30-40; col.4, table 1). The gel formulation having prolonged activity when compared to aqueous formulation and it is clear so that vision is not blurred (col.4, lines 1-5, col.7, lines 15-40).

US '392 teaches ophthalmic preparation for treatment of dry or irritated eye comprising vitamin A, cellulose derivatives and TWEEN, i.e. sorbitol in an amount of 0.1% to form an emulsion (abstract; col.1, lines 60-65; col.5, lines 29-40). The

composition serves to regenerate damaged epithelial cells and maintains osmotic balance similar to natural tear film (col.2, lines 5-11, 52-54).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an ophthalmic composition comprising small amount benzyllauryldimethylammonium chloride as disclosed by WO '597 and provide the composition in the form of gel comprising carboxypolymethylene polymer as disclosed by US '143, motivated by the teaching of US '143 that gel ophthalmic composition comprising carboxypolymethylene polymer has special viscosity and rheology making it free-flowing with prolonged activity when compared to aqueous formulation and it is clear so that vision is not blurred with reasonable expectation of having gel ophthalmic composition comprising benzyllauryldimethylammonium chloride and carboxypolymethylene polymer that has special viscosity and rheology making it free-flowing with prolonged activity when compared to aqueous formulation and it is clear so that vision is not blurred; and further one having ordinary skill in the art would have been motivated to add vitamin A and sorbitol and further cellulose derivative to the composition to provide emulsified artificial tear film as disclosed by US '392, motivated by the teaching of US '392 that ophthalmic composition comprising vitamin A, sorbitol and cellulose derivative serves to regenerate damaged epithelial cells and maintains osmotic balance similar to natural tear film, with reasonable expectation of having ophthalmic composition comprising benzyllauryldimethylammonium chloride, carboxypolymethylene polymer, vitamin A, cellulose derivatives and sorbitol that is free

flowing and serves to regenerate damaged epithelial cells and maintains osmotic balance similar to natural tear film.

The combination of the references does not teach the exact amounts of carboxypolymethylene polymer as claimed in claims 29 and 30, or the amount of sorbitol as claimed in claim 30. The claimed amounts do not impart patentability to the claims, absent evidence to the contrary.

Response to Arguments

10. Applicant's arguments with respect to claims 16-31, 33-37 have been considered but are moot in view of the new ground(s) of rejection.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. MSDS-OHS created 1989 disclosed in section 11 that concentration of 0.1% of dodecyldimethylbenzylammonium chloride, i.e. benzyllauryldimethylammonium chloride, causes mild discomfort in the eye that persisted for 2-3 hr. Therefore, concentration below 0.1% will be less discomfortable, and even low concentration as instantly claimed will not be irritating at all.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PATENT EXAMINER